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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,059

09/09/2004

Hoon Choi

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67283

7590

07/09/2008

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EXAMINER

ELLIS, SUEZU Y

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

07/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/507,059	Applicant(s) CHOI ET AL.	
	Examiner Suezu Ellis	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 12-19 and 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of invention I and species (i) in the reply filed on May 2, 2008 is acknowledged. The traversal is on the ground(s) that "the production of the composition is determinative of and directly relevant to the resulting composition and methods for its use, meaning that the claims should remain a single invention without restriction". This is not found persuasive because the inventions (the product and the method of making the product) require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-19 and 22-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 2, 2008.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states,

Art Unit: 1615

"the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings are objected to because the Brief Description of the Drawings discusses Figs. 2A and 2B, 3A and 3B, 4A and 4B. However, in Figs. 2-4, the figures are not labeled A and B.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 3, it appears that an essential element is missing in order for the oxides to be capable of inducing bone-like apatite growth. Therefore, it is unclear how the oxides are capable of inducing bone-like apatite growth. See MPEP § 2172.01.

With respect to claim 9, claim language recites "at least 30%-90% of the porous fibers are hollow". It is unclear what applicant means by "at least 30%-90%". From the claim language it appears that at least 90% of the porous fibers are hollow, however the claim provides a range of 30%-90%. Therefore it is unclear if applicant means that 30%-90% are hollow or at least 90% can be hollow. Please clarify. For examination purposes, claim language will be interpreted as "at least 30% of the porous fibers are hollow".

Claim 10 recites "at least 50% of the porous fibers are hollow". Therefore it appears 50-100% of the fibers can be hollow, however given the claimed range in claim 9, this is unclear. Please clarify. For examination purposes, claim language will be interpreted as "at least 50% of the porous fibers are hollow".

Art Unit: 1615

Claim 4 is indefinite due to its dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-7, 11, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahola et al. (WO 97/45367).

With respect to claims 1 and 5, Ahola et al. discloses a bioactive, biodegradable composite material comprising a fibrous composite of oxides and biodegradable polymers (polylactic acid), wherein fibers of the fibrous composite comprise gel-like oxide materials with nanometer-sized pores (pg. 5, lines 19-27; pg. 10, lines 1-10, 18-25; pg. 13, line 27 – pg. 14, line 1; pg. 14, lines 16-18).

With respect to claims 6 and 11, Ahola et al. discloses the inclusion of a drug or therapeutic composition to be delivered at a controlled rate from the fibrous composite (col. 4, lines 29-32; col. 10, lines 12-14, 26-30).

With respect to claim 7, Ahola et al. discloses the therapeutic composition comprises bone morphogenic protein (pg. 6, lines 10-11, 34-36).

With respect to claims 20 and 21, Ahola et al. discloses the drug or therapeutic composition is administered to an animal at a site needed (pg. 4, line 32 - pg. 5, line 5).

Claims 1-3, 5-8, 11, 20 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bellantone et al. (US 6,482,444).

With respect to claims 1 and 5, Bellatone et al. discloses a bioactive, biodegradable composite material comprising a fibrous composite of oxides and biodegradable polymers (polylactic acid), wherein fibers of the fibrous composite comprise gel-like oxide materials with nanometer-sized pores (col. 6, lines 36, 60-61; col. 7, lines 23-25; col. 8, lines 23-25).

With respect to claims 2 and 3, Bellatone et al. discloses the oxides comprise SiO₂ and CaO and are bioactive and capable of inducing bone-like apatite growth (col. 2, lines 51-65; col. 3, lines 46-50).

With respect to claims 6 and 11, Bellatone et al. discloses the inclusion of a drug or therapeutic composition to be delivered from the fibrous composite at a controlled rate (col. 7, lines 49-57; col. 15, lines 64-66).

With respect to claim 7, Bellatone et al. discloses the drug or therapeutic composition comprises bone morphogenic proteins (col. 7, lines 62-63).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bellantone et al. in view of Wu (US 6,465,052) and further in view of Canham (WO 97/06101).

With respect to claim 8, Bellantone et al. addresses all the limitations of claim 1, and further discloses the nanopores are large enough to allow diffusion of ions and nucleation of apatite crystallites (col. 3, lines 46-50; col. 6, lines 36-38; col. 15, lines 64-67), the composite having good mechanical properties and biodegradability (col. 1, lines 15-18, 24-33; col. 7, lines 37-42; col. 8, lines 23-26), and having mesopores (col. 6, line 36; col. 15, lines 50-51) and macropores (col. 6, lines 36-37). Since Bellatone et al. discloses the same structure as in the instant application, the structure of Bellatone et al. (mesopores and macropores) is considered to perform the same function as that of the instant application.

With respect to claims 20 and 21, Bellantone et al. discloses the drug or therapeutic composition is administered to an animal at a site needed (col. 9, lines 19-32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahola et al. in view of Hench et al. (US 2004/0009598).

With respect to claims 2 and 3, Ahola et al. addresses all the limitations of claim 1, and further discloses the oxide materials includes silica (SiO_2). However, Ahola et al. fails to expressly disclose the inclusion of other oxides. Hench et al. discloses it is well known for bioactive glass to comprise silicon dioxide and other oxides [0035]. It would have been obvious to one of ordinary skill in the art to modify the composition of the gel-like oxide materials in order to provide a suitable composite for a desired application (e.g. stimulate osteoblast proliferation) [0033]. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Examiner notes that since the oxides are the same as that in the instant application, they are functionally equivalent and therefore are capable of inducing bone-like apatite growth.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahola et al. in view of Hench et al. and further in view of the teachings of Li et al. (US 5,612,049).

With respect to claim 4, the modified Ahola et al. discloses the limitations of claims 1-3, and further discloses the oxides are modified with OH-groups (pg. 8, lines 1-2). While Ahola et al. fails to expressly disclose the OH groups being silanol or other metal-OH groups, it is well known in the art that bioactive glasses formed by sol-gel methods have silanol groups, as evidenced by Li et al. (col. 2, lines 7-21). Therefore,

Art Unit: 1615

the OH groups are considered functionally equivalent to silanol groups for the function of inducing bone-like apatite formation (col. 2, lines 7-10).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bellantone et al. in view of the teachings of Li et al.

With respect to claim 4, Bellantone et al. addresses all the limitations of claims 1-3, however fails to expressly disclose silanol and other metal-OH groups formed on the oxide surfaces. Li et al. teaches it is well known in the art that bioactive glasses formed by sol-gel methods have silanol groups (col. 2, lines 7-21). It would have been obvious to one of ordinary skill in the art to modify the oxides of Bellantone et al. to include silanol groups and similar metal-OH groups on the surfaces of the oxides in order to induce bone-like apatite formation (col. 2, lines 7-10).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahola et al. in view of Beaver et al. (US 4,748,121) and further in view of Slivka et al. (WO 98/53768).

With respect to claims 9 and 10, Ahola et al. addresses all the limitations of claim 1, however fails to expressly disclose the fibers being hollow. Beaver et al. teaches porous hollow silica-rich fibers comprising biochemically active material (drug) (col. 2, lines 22-50; col. 2, line 65 - col. 3, line 55). It would have been obvious to one of ordinary skill in the art to modify the porous fibers to be hollow in order to aid in cell and tissue infiltration, as taught by Slivka et al. (pg. 4, lines 28-29).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellantone et al. in view of Beaver et al. and further in view of Slivka et al.

With respect to claims 9 and 10, Bellantone et al. addresses all the limitations of claim 1, however fails to expressly disclose the fibers being hollow. Beaver et al. teaches porous hollow silica-rich fibers comprising biochemically active material (drug) (col. 2, lines 22-50; col. 2, line 65 - col. 3, line 55). It would have been obvious to one of ordinary skill in the art to modify the porous fibers to be hollow in order to aid in cell and tissue infiltration, as taught by Slivka et al. (pg. 4, lines 28-29).

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1615

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615